

Food and Drug Administration College Park, MD 20740

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JUN 1 9 2002

Aaron Tabor, M.D.
President
Physicians Laboratories
1031 E. Mountain Street
Building 302
Kernersville, North Carolina 27284

Dear Dr. Tabor:

This is in response to your letter of May 14, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submissions states that Physicians Laboratories is making the claim "Relief of allergy symptoms," among others, for the product **Revival Fresh** Herbals.

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statement that you are making for this product suggests that it is intended to treat, prevent, or mitigate a disease, namely, allergies. This claim does not meet the requirements of 21 U.S.C. 343(r)(6). This claim suggests that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

John B. Foret

Director

Division of Compliance and Enforcement Office of Nutritional Products, Labeling and Dietary Supplements Center for Food Safety

Center for Food Safety and Applied Nutrition

975-0163

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## Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300 FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of Enforcement, HFC-200 FDA, Atlanta District Office, Office of Compliance, HFR-SE140





May 14, 2002

Office of Special Nutritionals Center for Food Safety and Applied Nutrition Food and Drug Administration 200 C Street, SW (HFS-450) Washington, DC 20204

Dear Sir or Madam:

This letter will serve as notification pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994 that Physicians Laboratories is using the following statements on our herbal supplements under the following brand names: Revival Fresh Herbals.

Better memory & concentration

A positive, happy outlook

Better calmness/relaxation

More restful, peaceful sleep

Relief of allergy symptoms

Improved energy/stamina

Healthier immune function

Healthier liver function

Better prostate function

The above statements are accompanied by the required disclaimer pursuant to Section 6 of the Dietary Supplement Health and Education Act.

Sincerely,

Aaron Tabor, MD

President, Physicians Laboratories

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PHYSICIANS LABORATORIES

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